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10/500,109	01/12/2005	Michael Josephus Theresia Van Eijk	VAN EIJK-11	9167

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EXAMINER	
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ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,109	VAN EIJK ET AL.	
	Examiner	Art Unit	
	STEPHANIE K. MUMMERT	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on February 11, 2008 is acknowledged and has been entered. Claim 2 has been amended. Claims 28-39 have been canceled. Claims 1-27 are pending.

Claims 1-27 are discussed in this Office action.

Applicant's arguments, see p. 14-16, filed February 11, 2008, with respect to the rejection under Obviousness-type double patenting have been fully considered and are persuasive. The ground of rejection has been withdrawn.

All of the remaining amendments and arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This action is made FINAL.

Previous Rejections

The rejection of claims 2-8 and 16 as being indefinite is withdrawn in view of Applicant's amendment to the claims. The objection to the specification is withdrawn in view of Applicant's amendment to the specification.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-14 and 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schouten et al. (EP1130113; September 5, 2001) in view of Tang et al. (Nucleic Acids Research, 1995, vol. 23, no. 16, p. 3126-3131). Schouten teaches a method comprising multiplex ligation and detection assay (Abstract).

With regard to claim 1, Schouten teaches a method for determining the presence or absence of at least one target sequence (2) in a nucleic acid sample, comprising the steps of: a) providing to a nucleic acid sample a pair of a first oligonucleotide probe and a second oligonucleotide probe for each target sequence to be detected in the sample, whereby the first oligonucleotide probe has a section (4) at its 5'-end that is complementary to a first part (5) of a target sequence and the second oligonucleotide probe has a section (6) at its 3'-end that is complementary to a second part (7) of the target sequence, wherein , the first (5) and second part (7) of the target sequence are located adjacent to each other (Abstract, where a first probe is complementary to a first part of a target and a second probe is complementary to a second part of a target, each adjacent to the other; p. 3, paragraph 15-16), and wherein, the first and second oligonucleotide probes (4, 6) each comprise a tag sequence (8, 9) (Abstract, where the probes

comprise a tag that is non-complementary to the target; p. 3, paragraph 13, 18), which tag sequence

i) are essentially non-complementary to the target sequence (Abstract, where the probes comprise a tag that is non-complementary to the target; p. 3, paragraph 13, 18),

ii) comprise primer-binding sites (12,13) (p. 3, paragraph 18, where the tags are used to prime synthesis and where the primer is specific for the tag; see Abstract), and

wherein at least one of the tags further comprises a stuffer (11) (p. 4, paragraph 23, where size differences can be generated by introducing a stuffer region that is non-complementary to the target nucleic acid) and

b) allowing the oligonucleotide probes to anneal to the adjacent parts of target sequence so that the complementary sections (4,6) of the first and the second oligonucleotide probes are adjacent (Abstract, where a first probe is complementary to a first part of a target and a second probe is complementary to a second part of a target, each adjacent to the other; p. 3, paragraph 15-16, where the adjacent probes are ligated to one another);

c) providing means (14) for connecting the first and the second oligonucleotide probes annealed adjacently to the target sequence and allowing the complementary sections (4, 6) of the adjacently annealed first and second oligonucleotide probes to become connected, to produce a connected probe (15) corresponding to a target sequence in the sample (Abstract, where a first probe is complementary to a first part of a target and a second probe is complementary to a second part of a target, each adjacent to the other; p. 3, paragraph 15-16, where the adjacent probes are ligated to one another);

d) amplifying the connected probes from a primer pair (16, 17) to produce an amplified sample

(19) comprising amplified connected probes (20) (Abstract, p. 3, paragraph 15, where connected probes are amplified);

f) detecting the presence or absence of the target sequence by detecting the presence or absence of the detectable fragment by a detection method based upon molecular mass (p. 3, paragraph 19, where the various amplicons are discriminated based on size, or mass; see paragraph 148, where mass spectrometry is used to detect and identify amplification products).

With regard to claim 2, Schouten teaches an embodiment of claim 1, wherein the mass of a detectable fragment corresponding to a target sequence in a sample differs in-mass-from the mass of a detectable fragment corresponding to a different target sequence in the sample (paragraph 148, where mass spectrometry is used to detect and identify amplification products; paragraph 180, where in multiplex assays after template directed ligation, products are discriminated based on length or mass; paragraph 202, where the oligonucleotides for detecting wild type versus mutant sequence differ by at least 4 nucleotides).

With regard to claim 3, Schouten teaches an embodiment of claim 2, wherein the detectable fragment is denatured to provide a top single strand and a bottom single strand (paragraph 207, for example, where denaturation steps are included in the method).

With regard to claim 4, Schouten teaches an embodiment of claim 3, wherein the top strand stranded oligonucleotide comprising comprises the stuffer and wherein the bottom strand is essentially complementary to the top strand (p. 4, paragraph 23, where size differences can be generated by introducing a stuffer region that is non-complementary to the target nucleic acid and wherein the nucleic acid is double stranded and would inherently be complementary regarding top strand and bottom strand).

With regard to claim 5, Schouten teaches an embodiment of claim 3, wherein the mass of a top strand corresponding to one target sequence in a sample differs from the mass of the top strand corresponding to a different target sequence in the sample (paragraph 148, where mass spectrometry is used to detect and identify amplification products; paragraph 180, where in multiplex assays after template directed ligation, products are discriminated based on length or mass; paragraph 202, where the oligonucleotides for detecting wild type versus mutant sequence differ by at least 4 nucleotides).

With regard to claim 6, Schouten teaches an embodiment of claim 3, wherein the mass of a bottom strand corresponding to one target sequence in a sample differs from the mass of the bottom strand corresponding to a different target sequence in the sample (paragraph 148, where mass spectrometry is used to detect and identify amplification products; paragraph 180, where in multiplex assays after template directed ligation, products are discriminated based on length or mass; paragraph 202, where the oligonucleotides for detecting wild type versus mutant sequence differ by at least 4 nucleotides).

With regard to claim 7, Schouten teaches an embodiment of claim 3, wherein the difference in mass is due to provided by the mass of the stuffer in the top strand (p. 4, paragraph 23, where size differences can be generated by introducing a stuffer region that is non-complementary to the target nucleic acid and wherein the nucleic acid is double stranded and would inherently be complementary regarding top strand and bottom strand).

With regard to claim 9, Schouten teaches an embodiment of claim 1, wherein a primer capable of annealing to the primer-binding site in the detectable fragment comprises an affinity

label (paragraph 97, where the primer can comprise a modification such as the inclusion of a biotin label).

With regard to claim 10, Schouten teaches a method according to claim 9, wherein the top strands and/or the bottom strands comprise the affinity label (paragraph 181, lines 45-48, where the target nucleic acid can be tagged with biotin or digoxigenin).

With regard to claim 11, Schouten teaches an embodiment of claim 9, wherein the detectable fragment, the top strand or the bottom strand is purified or separated from the sample comprising the amplified connected probes using the affinity label (paragraph 181, lines 45-48, where the target nucleic acid can be tagged with biotin or digoxigenin and where, before or after hybridization, the tagged target nucleic acid can be separated).

With regard to claim 12, Schouten teaches an embodiment of claim 9, wherein the affinity label is biotin (paragraph 97, where the primer can comprise a modification such as the inclusion of a biotin label).

With regard to claim 13, Schouten teaches an embodiment of claim 1, wherein the detection method is based-on mass spectroscopic method (paragraph 148, where mass spectrometry is used to detect and identify amplification products).

With regard to claim 16, Schouten teaches an embodiment of claim 3, wherein a further mass difference in mass between top strands corresponding to different target sequences is created by incorporating different primer-binding sites in the oligonucleotide probes to which the different primers can anneal (paragraph 13, where the first and second tags may comprise different sequences; paragraph 18, where the tag comprises primer binding sequences).

With regard to claim 17, Schouten teaches an embodiment of claim l, wherein the tag of the oligonucleotide probes comprise said stuffer sequence with a mass from 0 to 20,000 daltons (p. 4, paragraph 23, where size differences can be generated by introducing a stuffer region that is non-complementary to the target nucleic acid).

With regard to claim 18, Schouten teaches an embodiment of claim 1, wherein the presence or absence of at least 10 different target nucleotide sequences is determined in a nucleic acid sample (paragraph 56, where the method can be used to detect 10-100 sites simultaneously).

With regard to claim 19. Schouten teaches an embodiment of claim l, wherein the length of the complementary section of the oligonucleotide probes is between 15 and 50 nucleotides (paragraph 17, where the length of the complementary region is at least 20 nucleotides).

With regard to claim 20, Schouten teaches an embodiment of claim 1, wherein the length of the primer-binding site is between 12 and 40 nucleotides (paragraph 18, where the tag comprising the primer binding site typically is of a length of at least 15 nucleotides, but can be any size).

With regard to claim 21, Schouten teaches an embodiment of claim 1, wherein the length of the tag is between 15 and 540 nucleotides (paragraph 18, where the tag comprising the primer binding site typically is of a length of at least 15 nucleotides, but can be any size).

With regard to claim 22, Schouten teaches an embodiment of claim 1, wherein the target nucleotide sequence contains a polymorphism (paragraph 24, 59, 152, where the target comprises a polymorphism, namely a SNP).

With regard to claim 23, Schouten teaches an embodiment of claim 1, wherein the target nucleotide sequence is a DNA molecule selected from the group consisting of: cDNA, genomic

DNA, a restriction fragment, an adapter-ligated restriction fragment, amplified adapter-ligated restriction fragments or AFLP fragments (paragraph 107, where the method can be performed on nucleic acids from all known organisms and all nucleic acid containing cells and the target can comprise DNA or RNA).

With regard to claim 24, Schouten teaches an embodiment of claim 1, further comprising a step for removing non-ligated probes (paragraph 14, where non-hybridized and non-ligated probes are removed prior to further analysis).

Regarding claim 1, Schouten does not teach that the tag sequence comprises a restriction site (10) for a restriction enzyme, or step (A) which restriction site (10) is located between the primer-binding site and the section of the oligonucleotide probe (4, 6) that is complementary to the first (5) or second part (7) of the target sequence. Schouten also does not teach step e) digesting the amplified connected probes with the restriction enzyme to produce a detectable fragment (21). Tang teaches a method of mass spectroscopic analysis of DNA probes and includes a teaching of the inclusion of restriction sites for cleavage of tags (Abstract, p. 3130, col. 2).

With regard to claim 1, Tang in view of Schouten teaches a method comprising sequence comprises a restriction site (10) for a restriction enzyme, and also teaches (A) which restriction site (10) is located between the primer-binding site and the section of the oligonucleotide probe (4, 6) that is complementary to the first (5) or second part (7) of the target sequence (where first it is noted that Schouten teaches the format of the tag sequence, comprising a primer binding site; Tang teaches that restriction sites could be positioned next to the primer site and most of the

primer site is cut off prior to mass spectrometry; see p. 3130, col. 2, 'potential applications in molecular biology' heading); and

e) digesting the amplified connected probes with the restriction enzyme to produce a detectable fragment (21) (p. 3130, col. 2, 'potential applications in molecular biology, where Tang teaches that restriction sites could be positioned next to the primer site where most of the primer site is cut off prior to mass spectrometric analysis).

With regard to claim 8, Tang in view of Schouten teaches an embodiment of claim 3, wherein the top strands and/or the bottom strands corresponding to different target sequences in the sample differ in mass by more than 1 Dalton (see Figure 2 and 3, where the difference in masses between different targets is more than 1 Dalton).

With regard to claim 14, Tang in view of Schouten teaches an embodiment of claim 1, wherein the restriction enzyme is a restriction endonuclease (p. 3130, col. 2, 'potential applications in molecular biology' heading, where Tang teaches that restriction sites could be positioned next to the primer site where most of the primer site is cut off prior to mass spectrometric analysis).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have extended the teachings of Schouten to incorporate the restriction site into the mass spec analysis as taught by Tang to arrive at the claimed invention with a reasonable expectation for success. As taught by Tang, "a restriction site could be positioned such that most of the known primer sequence is cut off prior to mass spectrometry. Thus actual and valuable sequence information could be obtained, even if only short Sanger ladders are produced and analyzed" (p. 3130, col. 2, 'potential applications in molecular biology' heading). Therefore,

one of ordinary skill in the art at the time the invention was made would have been motivated to have extended the teachings of Schouten to incorporate the restriction site into the mass spec analysis as taught by Tang to arrive at the claimed invention with a reasonable expectation for success.

3. Claims 15 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schouten et al. (EP1130113; September 5, 2001) in view of Tang et al. (Nucleic Acids Research, 1995, vol. 23, no. 16, p. 3126-3131) as applied to claims 1-14 and 16-24 above and further in view of Vos et al. (Nucleic Acids Research, 1995, vol. 23, p. 4407-44014). Schouten teaches a method comprising multiplex ligation and detection assay (Abstract).

Schouten in view of Tang teach the limitations of claims 1-24. Neither Schouten or Tang teach the inclusion of a selective primer during the amplification step. Vos teaches a method of selective amplification of restriction fragments (Abstract).

With regard to claim 15, Vos teaches an embodiment of claim 14, wherein the restriction endonuclease is a rare cutter (p. 4409, 'principle of the method' heading, where the fragments for amplification are generated by a rare cutter at one end and a frequent cutter at the other end).

With regard to claim 25, Vos teaches an embodiment of claim l, wherein at least one of the primers is a selective primer (p. 4408, col. 1, 'AFLP primers and adapters' heading, where AFLP primers consist of three parts, including a selective extension; p. 4409, col. 1, where selective nucleotides are included at the 3' end of PCR primers, only restriction fragments where the nucleotides flanking the site match the selective nucleotides will be amplified).

With regard to claim 26, Vos teaches an embodiment of claim 25, wherein the selective primer comprises:

i) a section that is complementary to at least part of the primer-binding site (p. 4408, col. 1, where the primers are complementary to the primer binding site and comprise additional sequences), and

ii) a selective section of one to 10 selective nucleotides, located immediately adjacent, to the 3' end of the section of (i) (p. 4408, col. 1, 'AFLP primers and adapters' heading, where AFLP primers consist of three parts, including a selective extension; p. 4409, col. 1, where selective nucleotides are included at the 3' end of PCR primers, only restriction fragments where the nucleotides flanking the site match the selective nucleotides will be amplified).

With regard to claim 27, Vos teaches an embodiment of claim 26 wherein the section of (i) is complementary to 5 or more nucleotides that form a part of the primer-binding that is located immediately adjacent to the nucleotides complementary to the selective section of the primer (p. 4408, col. 1, 'AFLP primers and adapters' heading, where AFLP primers consist of three parts, including a selective extension; p. 4409, col. 1, where selective nucleotides are included at the 3' end of PCR primers, only restriction fragments where the nucleotides flanking the site match the selective nucleotides will be amplified).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have extended the method of Schouten and Tang to incorporate the selective primer of Vos to arrive at the claimed invention with a reasonable expectation for success. As taught by Vos, "selective amplification is achieved by the use of primers that extend into the restriction fragments, amplifying only those fragments in which the primer extensions

match the nucleotides flanking the restriction sites" and "allows the specific co-amplification of high numbers of restriction fragments" (Abstract). Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to have extended the method of Schouten and Tang to incorporate the selective primer of Vos to arrive at the claimed invention with a reasonable expectation for success.

Response to Arguments

Applicant's arguments filed February 11, 2008 have been fully considered but they are not persuasive. First, it is noted that Applicant's thorough response is appreciated. However, upon a careful reading of Applicant's response, it appears that Applicant is mischaracterizing the combined teachings of Schouten and Tang. Applicant, in brief, explains the position of the office and reiterates their invention. Applicant digests the amplicon "to provide a small, detectable fragment comprising the stuffer sequence" (see also Diagram 4, p. 10 of remarks). Applicant notes "this small detectable fragment does not include the 'complementary sequence'" and notes "the stuffer sequence imparts a unique mass to each detectable fragment in the sample" to allow for identification of nucleic acids in a sample (p. 10 of remarks).

Regarding Schouten, Applicant asserts "the probe of Schouten differs from the present probe in that the tag sequence does NOT comprise a restriction endonuclease site located between the stuffer and the complementary sequence" and notes the "difference is that MS now becomes a feasible and reliable technique for determining the presence (or absence) of a target sequence in a nucleic acid sample" because the detected fragment is very small and comprises the primer binding sequence and the stuffer sequence, but not the complementary sequence.

Regarding Tang, Applicant asserts that Tang teaches "a restriction site could be positioned such that most of the known primer sequence is cut off prior to mass spectrometry" (p. 12 of remarks). Applicant then goes on to exemplify the combination in Diagram 3. However, this interpretation of the combination of references takes a narrow view of the broad teachings of Schouten and a narrow view of the suggestion by Tang. Schouten teaches that the oligonucleotide produced for the probe can be produced by restriction enzyme digestion (paragraph 60) and therefore would include a restriction site within the tag portion. Schouten also teaches that the products can be detected by mass spec (paragraph 148) and that each stuffer sequence is different and is used to identify the associated nucleic acid target by adding specific length and therefore additional mass to the ligated products (paragraph 120-121, specifically lines 44-46), much like Applicant's invention. In the same vein, Schouten also teaches that the amplified products can be digested prior to further analysis (paragraph 146). Therefore, restriction digestion can be included in certain embodiments of the method disclosed by Schouten.

Regarding Tang, prior to the teaching that the primer sequence can be cut off, Tang notes both that "genomic DNA can be digested into small fragments" and "the five base overhang also serves as a primer for subsequent Sanger sequencing" and therefore, in the context of the overall teaching of Tang, the cleavage is intended to remove sequence that has already been obtained, and therefore to present the smallest fragment for analysis as possible. Yes, Tang indicates that the primer sequence is removed, but in combination with Schouten, Tang does not represent a teaching away as indicated by Applicant. Instead, Tang provides a suggestion to make the fragment for detection, as short and specific as possible. In combination with the tagged probes

of Schouten, including primer sites and specific and distinguishable stuffer sequences, it would have been prima facie obvious to add the restriction site and cleavage technique taught by Tang, but to analyze the restricted fragment to arrive at the claimed invention through the stated combination of references.

The rejection is maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHANIE K. MUMMERT whose telephone number is (571)272-8503. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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